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10/722,318	11/25/2003	Tamiko Sadaie	2793	9319

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,318

Applicant(s)

SADAIE, TAMIKO

Examiner

Lora E. Barnhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

The examiner notes the cancellation of claims 1-5 and 7 and the addition of claims 9-14. Claims 6 and 8 remain withdrawn as being drawn to a non-elected invention. This Office action pertains to claims 9-14 ONLY.

Specification

The objection to the specification made in the Office action of 2/1/05 is withdrawn in light of the amendments to the specification.

The amendment filed 5/12/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: The ATCC number for *Methylosinus tricosporium* has been changed from ATCC35070 to ATCC49242. Applicants allege that the ATCC number given in the original disclosure was "incorrect" but have provided no reason why this was the case or evidence to document the error. The numbers are not similar in any way, so the examiner cannot reasonably assume that a typographical error was made. While the examiner agrees that ATCC49242 is indeed a deposit of *M. tricosporium*, this fact fails to justify support the addition of the new matter to the disclosure. Applicant is required to cancel the new matter in the reply to this Office Action.

The ATCC numbers recited in the specification at page 5 are clearly not “exemplary strains” of the invention. The disclosure recites, “**In the concrete**, the microbe group of the invention includes...[the] following organisms”, followed by a list of fungal and bacterial species with corresponding ATCC accession numbers. The use of the term “in the concrete” would clearly preclude anyone reading the instant disclosure from interpreting the list of accession numbers as “examples”, as is currently argued by counsel (page 19, lines 9-15).

In addition, the amendment to replace the original accession numbers in the as-filed specification with different accession numbers introduces new matter into the specification. This material should be cancelled.

Claim Objections

The objections to the claims are withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112

The rejections of the claims under 35 U.S.C. 112, first and second paragraph, are withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 101

Claims 9-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As noted on the first Office action, the standard for patentability in the area of living organisms and biomolecules is whether the claimed matter “is the result of human intervention.” See M.P.E.P. § 2105. Claim 9 is drawn to a mixture of several fungi and bacteria produced by growing said mixture with “electron acceptors” and “carbon sources” in an environment in which the oxygen concentration is

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maintained at 1ppm or less. Applicant has asserted that claim 9 recites a “special mixture” that necessitates the hand of man; this argument has been fully considered but is not persuasive for the invention **as claimed**.

The examiner points out that all of the steps recited in claim 9 are, in fact, natural processes. In latrines and compost piles, for example, fungi and bacteria grow naturally on the carbon sources and electron acceptors naturally present in waste; the fungi and bacteria at the bottom of the mixture would certainly be growing in an anaerobic or microaerobic environment of 1ppm or less oxygen. There are simply no active steps recited in the instant claims that **necessitate** human intervention. Claim 13 includes an “aeration” step, but the only requirement for said step is that it results in a microaerobic (1ppm to 0.001ppm oxygen) or anaerobic (0ppm) environment. The naturally-occurring biomass within a latrine or compost pile is stirred, and therefore aerated, every time waste is added thereto, for example, without appreciably disturbing the fungi and bacteria at the bottom of the biomass. Claim 14 merely recites inherent properties of the recited fungi and bacteria and does not add active method steps to the process. In short, the claimed **composition** does not necessitate the hand of man and, as such, is directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

The rejection of the claims under 35 U.S.C. 102(b) as being anticipated by U.S. '634 taken in light of U.S. '929 is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 103

Claims 9-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '634 taken with U.S. '929 and U.S. '736. The claims are drawn to a mixture of several fungi and bacteria produced by growing said mixture with electron acceptors (*i.e.*, inorganic salts) and carbon sources in an environment in which the oxygen concentration is maintained at 1ppm or less. In some dependent claims, the inorganic salt comprises nitrate and sulfate and the carbon source comprises cellulose or hemicellulose. In some dependent claims, the mixture is aerated while maintaining the oxygen concentration at 1ppm or less. Claim 14 specifies the manner in which the fungi and bacteria in the mixture act on organic waste material.

Response to Arguments

As detailed in the Office action mailed 2/1/05, U.S. '634 teaches a composition comprising *Mucor hiemalis* and various bacteria from numerous families (Example 1). U.S. '634 further teaches that said composition can grow in anaerobic or microaerobic conditions and can subsist on domestic kitchen waste (Example 11; column 6, lines 8-14).

As was pointed out in the Office action mailed 2/1/05, The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' composition differs, and if so to what extent, from the composition discussed in U.S. '634. Therefore, the burden of establishing novelty or unobviousness by **objective evidence** is shifted to applicants.

Again, the language of new claim 9 ("comprising") does not exclude the possibility that the claimed composition comprises one or all of the bacteria and fungi of Example 1 of U.S. '634. The claimed composition and the composition of U.S. '634 share similar components (a *Mucor* fungus and various bacteria symbiotic to it) and properties (ability to survive in low-oxygen environments and to subsist on organic waste), so there is a reasonable probability that it is either identical or sufficiently similar to the claimed mixture that whatever differences exist are not patentably significant.

Applicant has argued that since the composition of U.S. '634 comprises yeast (for example, *Saccharomyces cerevisiae*), U.S. '634 is not appropriate prior art (page 22). This argument has been fully considered, but it is not persuasive. It is noted that in claim 9, for example, Applicant recites the phrase "comprising", which is open-claim language. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and **does not exclude additional, unrecited elements** or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). See M.P.E.P. § 2111.03. Applicants have not set forth any **evidence** that the instantly claimed composition specifically excludes yeast. Table 1 discloses numerous species detected within the composition, but nowhere in the disclosure is taught that yeast were assayed and found to be lacking. In fact, applicants admit within the specification as filed that microorganisms other than those recited in claim 9 are present; page 5 of the disclosure teaches that said microorganisms are merely the "predominant" microbes in the claimed composition (lines 9-19).

Applicant has further argued that the composition of U.S. '634 was derived from anaerobic growth, while the instant composition is made by "aeration...with the dissolved oxygen concentration maintained at 1ppm or less" (pages 22-23). Again, this argument has been fully considered, but it is not persuasive. The language "1 ppm **or less**" clearly reads on an anaerobic environment such as that described in U.S. '634. Additionally, it is noted that no aeration step is required for claims 9-12 and 14.

Applicant asserts that the activity of the claimed mixture on organic waste compared with the similar activity of the U.S. '634 mixture is immaterial to the question of patentability (page 23); the examiner disagrees. Absent a **substantive evidentiary showing** (*i.e.*, not merely arguments of counsel) that the composition of U.S. '634 possesses or lacks properties and characteristics possessed by the instant composition, it is impossible to determine from the instant disclosure and claims whether the instant composition differs in a patentable manner from the composition of U.S. '634. By applicant's own admission, "what is perceived to be a genus by one person may be perceived as being merely a species by another systematist" (Information from ATCC, IDS of 5/12/05; page 36 of original FAX transmission with heading "Bacterial Strains"). Taxonomic classification of microorganisms is, according to the ATCC, a subjective process. In short, the fact that the inventors of U.S. '634 classified the fungi of their composition as *Mucor hiemalis* does not exclude the possibility that said fungi are actually *Mucor indicus*, or vice versa. Again, the burden of establishing novelty or unobviousness by **objective evidence** is shifted to applicants.

Applicants' interpretations of the examiner's use of the U.S. '929 and U.S. '736 references are inaccurate. These references were cited simply for their teachings that nitrate (added as salt or produced naturally from naturally present ammonia) facilitates the decomposition of sewage (see pages 9 and 10 of first Office action). Because the composition of U.S. '634 is disclosed as being useful for such a process, the skilled artisan would certainly be motivated to add nitrate to the composition of U.S. '634 for the expected benefit of improved activity in the decomposition of sewage so taught by U.S. '929 and U.S. '736. If nothing else, the teachings of U.S. '929 and U.S. '736 are evidence that it was well known in the art at the time the invention was made that the presence of nitrate facilitates decomposition of sewage by microorganisms. The rejection, therefore, is proper, and it is **maintained**.

Conclusion

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart, whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn, can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

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Irene Marx

**IRENE MARX
PRIMARY EXAMINER**